



ATTORNEY DOCKET NO.: 2003946-0057

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Kowalczyk, et al. Examiner:  
Serial No.: 10/667,864 Art Unit:  
Filing Date: September 22, 2003  
Title: HEMIASTERLIN DERIVATIVES AND USES THEREOF

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**STATEMENT**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

**Type of Statement**

The present Information Disclosure Statement is:

- ☒ An *original* Information Disclosure Statement; or  
☐ A *supplemental* Information Disclosure Statement.

**Certificate of Mailing**

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

December 23, 2003

Date

Signature

Sandra Saccoccia

Typed or Printed Name of person signing certificate

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
  - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☒ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
  - ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

☒ A copy of each cited reference not indicated with an asterisk is included;

☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

☐ Does not contain non-English language citations;

☐ Does contain non-English language citations, of which the following is a concise

explanation:

[ ] Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

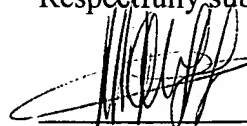
The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,



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Dated: December 23, 2003

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<b>FORM PTO-1449</b> (REV. 8-83) <b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>		U.S. Department of Commerce Patent and Trademark Office	Atty. Docket: 2003946-0057	In Re Application No.: 10/667,864
			Applicant: Kowalczyk, et al.	
			Filing Date: September 22, 2003	Group:
	4296, 1992.			
	Nieman, et al., "Synthesis and Antimitotic/Cytotoxic Activity of Hemiasterlin Analogues", <i>J. Nat. Prod.</i> 66: 183-189, 2003.			
EXAMINER			DATE CONSIDERED	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.				

Atty. Docket: 2003946-0057 In Re Application No.: 10/667,864

Applicant: Kowalczyk, et al.

Filing Date: September 22, 2003

Group:

### U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	6,153,590	Andersen et al.	November 28, 2000	514	19
	6,143,721	Janssen et al.	November 7, 2000	514	16
	5,661,175	Kashman et al.	August 26, 1997	514	419

### U.S. PATENT APPLICATIONS

Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:

### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
	DE 40 16 994	Germany	28 November 1991		
	JP 8-73444	Japan	19 March 1996		
	WO 96/33211	PCT	24 October 1996		
	WO 97/43305	PCT	20 November 1997		
	WO 98/13375	PCT	02 April 1998		
	WO 99/31122	PCT	24 June 1999		
	WO 99/32509	PCT	01 July 1999		
	WO 01/18032	PCT	15 March 2001		
	WO 03/008378	PCT	30 January 2003		

### OTHER DOCUMENTS

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Anderson, et al., "Total Synthesis of (-) Hemiasterlin, A Structurally Novel Tripeptide that Exhibits Potent Cytotoxic Activity", <i>Tetrahedron Letters</i> , <b>38</b> (3): 317-320, 1997.
	Billson, et al., "The Design and Synthesis of Inhibitors of the CysteinyI Protease, Der P I.", <i>Bioorganic &amp; Medicinal Chemistry Letters</i> , <b>8</b> : 993-998, 1998.
	Dragovich, et al., "Stucture-Based Design, Synthesis, and Biological Evaluation of Irreversible Human Rhinovirus 3C Protease Inhibitors. 1. Michael Acceptor Structure-Activity Studies", <i>J. Med. Chem.</i> <b>41</b> : 2806-2818, 1998.
	Hauske, et al., "Design and Synthesis of Novel FKBP Inhibitors", <i>J. Med. Chem.</i> <b>35</b> : 4284-